



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day Comment Request; Population Assessment of Tobacco and Health (PATH) Study – 3rd Wave (NIDA)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on February 11, 2015, pages 7619 -7620 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_Submission@omb.eop.gov or by fax to (202) 395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443-8755 or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Population Assessment of Tobacco and Health (PATH) Study – Third Wave of Data Collection – 0925-0664 - Revision, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925-0664, expires 9/30/2016) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the third wave of data collection. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The Study conducts annual interviews and collects biospecimens from adults to assess within-person changes

and between-person differences in tobacco-product use behaviors and related health conditions over time. Its longitudinal, population-based data will help to enhance the evidence base that informs FDA’s regulatory actions under the Family Smoking Prevention and Control Act to protect the Nation’s public health and reduce its burden of tobacco-related morbidity and mortality.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 54,434.

Estimated Annualized Burden Hours

Form or Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Adult Extended Interview	Adults	25,444	1	1	25,444
Consent for Adult Extended Interview	Adults	2,046	1	4/60	136
Adult Extended Interview (Aged-up)	Adults	1,780	1	68/60	2,017
Consent for Biological Samples	Adults	1,780	1	5/60	148
Biospecimen Collection: Urine	Adults	13,805	1	10/60	2,301

Biospecimen Collection: Blood	Adults	765	1	18/60	230
Tobacco Use Form	Adults	14,570	1	5/60	1,214
Follow-up/Tracking Participant Information Form for Adults	Adults	27,224	2	8/60	7,260
Youth Extended Interview	Youth	9,625	1	35/60	5,615
Assent for Youth Extended Interview	Youth	1,923	1	3/60	96
Youth Extended Interview (Aged-up)	Youth	1,923	1	45/60	1,442
Parent Interview	Parents	9,818	1	16/60	2,618
Parent Permission and Consent for Parent Interview	Parents	2,161	1	5/60	180
Parent Interview (Aged-up)	Parents	1,961	1	19/60	621
Verification Interview	Adults	35,564	1	2/60	1,185
Validation Interview	Adults	3,579	1	4/60	239
Follow-up/Tracking Participant Information Form for Youth	Parents	11,548	2	8/60	3,079

Follow-up/Tracking Participant Information Form for Sample Shadow Youth	Parents	2,282	2	8/60	609
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Dated: June 12, 2015.

Genevieve deAlmeida-Morris,
Project Clearance Liaison,
NIDA, NIH.

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